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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,971	12/08/2000	David M. Anderson	016754/0206	1748

7590

07/24/2002

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EXAMINER

RAO, MANJUNATH N

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 07/24/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/731,971

Applicant(s)

ANDERSON ET AL.

Examiner

Manjunath N Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 21-31 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 7. 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-33 are still at issue and are present for examination. Claims 1-20 and 32 are now under consideration. Claims 21-31 and 33 have been withdrawn from consideration as they belong to non-elected subject matter.

Election/Restrictions

Applicant's election of Group I, claims 1-20 and 32 (but not claim 31 as indicated in their response) in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Sequence Compliance

Applicant is required to comply with the sequence rules by inserting the sequence identification numbers of all sequences recited within the claims and/or specification. It is particularly noted that applicants have failed to provide SEQ ID NO: to oligonucleotide sequences described in page 18, lines 7 and 8. See particularly 37 CFR 1.821(d).

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Claim Objections

Claims 10, 14, 15 are objected to because of the following informalities: Claims 10, 14, 15 depend from a single claim but address the depending claim in plurals. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 14, 16-18, 20 and 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Kuppe et al. (J. Bacteriol., 1989, Vol. 171(11):6077-6083). This rejection is based upon the public availability of a printed publication. Claims 1-10, 14, 16-18, 20 and 32 of the instant application is drawn to a composition comprising a) an enzyme that cleaves a linkage that effects release of a cell-surface protein or carbohydrate, said enzyme being other than an endo-1,4-D-mannase, and b) a physiologically acceptable carrier for said enzyme, wherein said composition is in form suitable for oral administration, wherein said enzyme effects a release of a cell-surface protein, wherein said composition contains no other anti-infection agent, wherein said composition is a feed, wherein said enzyme is selected from a group consisting of sphingomyelinase and phospholipases which are of type C (PLC) or type D and is phosphatidylinositol-specific phospholipase C, wherein the enzyme carrier is a food stuff and wherein the composition is a solid or a liquid formulation and wherein the enzyme is prepared

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from *B.cereus* strains such as ATCC 7004 or ATCC6464, wherein the enzyme is alternatively obtained by expression of recombinant DNA in a host and the enzyme is represent at 200 IU/kg to 4000 IU/kg feed. Kuppe et al. disclose such a composition comprising a purified or recombinantly produced phospholipase C enzyme of *B.cereus*. The composition disclosed by Kuppe et al. is in the form a liquid (culture medium of the host cell expressin ghte recombinant enzyme in milligram quantities) comprising a carrier such as beef extract or tryptone or NaCl which is recognized as a fedd or food in the art. Therefore, Kuppe et al. anticipate claims 1-10, 14, 16-18, 20 and 32 as written.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuppe et al. (J. Bacteriol., 1989, Vol. 171(11):6077-6083) and Barbis et al. (Brazilian J. Med. Biol. Res., 1994, Vol. 27:401-407, A14 on IDS). Claims 1-20 and 32 in this instant application are drawn to a composition comprising a) an enzyme that cleaves a linkage that effects release of a cell-surface protein or carbohydrate, said enzyme being other than an endo-1,4-D-mannase, and b)a physiologically acceptable carrier for said enzyme, wherein said composition is in form suitable for oral administration, wherein said enzyme effects a release of a cell-surface protein, wherein said composition contains no other anti-infection agent, wherein said composition is a feed,

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wherein said enzyme is selected from a group consisting of sphingomyelinase and phospholipases which are of type C (PLC) or type D and is phosphatidylinositol-specific phospholipase C, wherein the enzyme carrier is a food stuff and wherein said food stuff is an animal feed comprising grains such as sorghum, wheat etc. and wherein the composition is a solid or a liquid formulation and wherein the enzyme is prepared from *B.cereus* strains such as ATCC 7004 or ATCC6464, wherein the enzyme is alternatively obtained by expression of recombinant DNA in a host such as *B.megaterium* and the enzyme is represent at 200 IU/kg to 4000 IU/kg feed. Thus it appears that applicants invention comprises making animal feeds incorporated with the phospholipase enzyme derived from *B.cereus* which takes the place of an antibiotic in order to reduce the use of antibiotics in animal feeds.

Kuppe et al. teach the purification and characterization of PLC from *B.cereus*. The reference also teaches the amino acid sequence and the polynucleotide sequence of the gene encoding the enzyme. The reference teaches the isolation of the enzyme from *B.cereus* ATCC 6464 and demonstrates that the enzyme is a phosphatidylinositol-specific PLC. However, the reference does not exclusively teach that the enzyme is capable of cleaving a cell surface protein even though it does teach, that in mammals, it plays a key role in transmembrane signal transduction involving Ca^{2+} mobilizing growth factors and hormones (see introduction). Also, the reference does not teach the use of the enzyme in animal feed.

Barbis et al. teach that a number of cell surface molecules (including proteins) are anchored in the cell membrane by glycosylphosphatidylinositol (GPI) and that these molecules are involved in various properties of the cell. The reference also clearly teaches that many GPI-anchored proteins on the cell membrane can be released by treatment with phosphoinositol-

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specific PLC. The same reference also teaches that a variety of such GPI-anchored molecules on cell surfaces act as cellular receptors for enveloped or non-enveloped viruses. The reference further teaches canine parvo virus (CPV) binds to a protein moiety which is a GPI-anchored protein on the cell surface. The reference teaches that pretreatment of such cells with PLC removed the GPI-anchored proteins from the cell surface rendering them resistant to infection by the CPV virus. In essence, the reference teaches that PLC treatment of cells can render them resistant to virus infection.

Armed with the above two references, it would have been obvious to one of ordinary skill in the art to combine the two, i.e., use the purified enzyme/recombinant enzyme composition provided by Kuppe et al. to fortify animal an animal feed such that the animal consuming such feed would be imparted with a mechanism to avoid viral infection, for example, especially those viruses that attach through the cells of the intestinal tract. The added PLC in the feed would rid the intestinal cells of the GPI anchoring proteins that would otherwise aid the viruses to infect the intestinal cells. Using the cDNA clone provided by Kuppe et al. it would also have been obvious to one of ordinary skill in the art to sub-clone the above enzyme and produce it by recombinant methods using any of the host cells including *B.megaterium* and such recombinant methods are widely known and used in the art of molecular biology. One of ordinary skill in the art would be motivated to do so to reduce the dependency on drugs for treatment of such infections. One of ordinary skill in the art would have a reasonable expectation of success since Kuppe et al. provide a purified/recombinant enzyme from *B.cereus* and the reference of Barbis et al. clearly teach the role of PLC enzyme in preventing viral infection.

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Therefore the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 6:30 a.m. to 3:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014.

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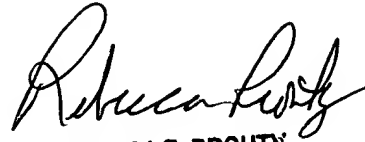
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Manjunath N. Rao Ph.D.

7/23/02


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